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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/863,600	05/23/2001	Virginia Smith-Swintosky	PRI-0014 (ORT-1436)	9298

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EXAMINER	
MOHAMED, ABDEL A	

ART UNIT	PAPER NUMBER
1653	

DATE MAILED: 04/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/863,600	SMITH-SWINTOSKY ET AL.	
	Examiner	Art Unit	
	Abdel A. Mohamed	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 February 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *38-52* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *38-52* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

ACKNOWLEDGMENT OF AMENDMENT, REMARKS AND STATUS OF THE CLAIMS

1. The amendment and remarks filed 2/17/04 are acknowledged, entered and considered. In view of Applicant's request claims 1-22 have been canceled and claims 38-52 have been added. Thus, claims 38-52 are now pending in the application. The objection to the trademarks and the rejections under 35 U.S.C. 112, second paragraph and 35 U.S.C. 103(a) over the prior art of record are withdrawn in view of Applicant's cancellation of the claims, amendment and remarks filed 2/17/04. However, the rejection under 35 U.S.C. 112, first paragraph is maintained for the reasons of record.

CLAIMS REJECTION-35 U.S.C. 112 1st PARAGRAPH.

2. Newly submitted claims 38-52 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for employing peptides comprising one or more monomeric peptides that bind to erythropoietin (EPO) receptor and use of said peptides in designing, synthesizing and testing of biological activity toward the EPO receptor *in vitro*, does not reasonably provide a method for treating a patient having a condition mediated by neurotoxicity, neurodegeneration or neurological damage by administering to said patient (which include humans) therapeutically effective amount of the specific compounds in the manner claimed in claims 38-51, and to a method of promoting neurite outgrowth in a patient having a condition mediated by neurotoxicity, neurodegeneration or neurological damage by administering to said

patient effective amount of the specific compounds as claimed in claim 52. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The specification does not adequately teach a method for treating or promoting neurite outgrowth in a patient having a condition mediated by neurotoxicity, neurodegenaration or neurological damage, comprising administering to said patient a therapeutically effective amount of a peptide comprising one or more monomeric peptides as presently claimed in claims 38-52; rather, the specification teaches the expression of rhEPO in primary rat neuronal cultures and in neuronal cell lines (Example 1), EPO induced gene expression in PC12 cells (Example 2), rhEPO neuroprotection and neurite outgrowth effects on rat hipocampal and cortical cell and PC12 cells (Example 3), assays to show that EPO mimetic peptides stimulate neurite outgrowth in cell culture (Example 4), and assays to determine that EPO protects against ischemic injury in rats (Example 5).

Therefore, the instant specification does not commensurate with the claimed subject matter in which the peptides tested for biological activity against EPO receptors *in* vitro is expected to be particularly useful in the treatment of a patient having a condition mediated by neurotoxicity, neurodegeneration or neurological damage which encompass the various diseases and conditions recited on page 16, lines 27 to page 18, lines 30. Examples of the chronic neurodegenerative disorders, or diseases, or conditions intended to be treated by the peptides of the present invention include, but

are not limited to, Alzheimer's disease, Pick's disease, diffuse Lewy body disease, progressive spranuclear palsy (Steel-Richardson syndrome), multisystem degeneration (SHY-Drager syndrome), chronic epileptic conditions associated with neurodegeneration, motor neuron diseases including amyotrophic lateral sclerosis, degenerative ataxias, cortical basal degeneration, ALS-Parkinson's-Dementia complex of Guam, subacute sclerosing panencephalitis, Huntington's disease, Parkinson's disease, etc. Examples, of acute neurodegenerative disorders include, but are not limited to, various types of acute neurodegenerative disorders associated with neuronal cell death or compromise including cerebrovascular insufficiency, focal or diffuse brain trauma, diffuse brain damage, and spinal cord injury. With respect to the limitation of a condition mediated by neurotoxicity (claims 38 and 52), the claimed invention as recited on page 18, lines 10 to 15 in the instant specification contemplates the treatment and/or prevention of neurological and neuropsychiatric manifestations resulting from chemical, toxic, infections and radiation injury of the nervous system and as a result of prematurity, as well as the treatment and/or prevention of neurological and neuropsychiatric consequences of encephalopathies including, but not limited to, those of anoxic-ischemia, hepatic, glycemic, uremic, electrolyte and endocrine origin. Thus, there is no working example(s) or evidence or data to show that a similar regimen can be used for treating a patient (including a human) having a condition mediated by neurotoxicity, neurodegeneration or neurological damage such as Alzheimer's disease, Parkinson's disease, Huntington's disease, cerebrovascular insufficiency, anoxic-ischemia, etc., (as recited above) by administering to said patient a therapeutically

effective amount of a peptide comprising one or more monomeric peptides, wherein each of the said monomeric peptides comprises the specific compounds in the manner claimed in claims 38-52.

Thus, in view of the above, and in view of the fact that there is no enablement in the instant specification for the method of treating diseases or conditions of the nervous system in patients by administration of compositions having neurological therapeutic activity of EPO compound claimed, and further in view of the complexity of Applicant's invention and the state of the art of treating and/or promoting neurite outgrowth of neurodegenerative disorders such as Alzheimer's disease, Parkinson's disease, Huntington's disease, cerebrovascular insufficiency, anoxic-ischemia, etc. with the specific compounds claimed; the Examiner is unable to determine the enablement of the invention as claimed without appropriate working example(s) or evidence or data. Such evidence in the art of treating cognitive dysfunctions details the state of the art in this area and establishes that even some of the diseases such as Alzheimer's disease are very hard to diagnose, let alone to treat and/or promote neurite outgrowth in a patient having the above conditions (i.e., neurotoxicity, neurodegeneration, or neurological damage). For example, Ezzell (Scientific America, pages 152-153, March 7, 1993) states on page 152, middle column, before last paragraph that doctors can only diagnose Alzheimer's through a process of elimination, ruling out other disorders such as a slight stroke, a brain tumor, or even an adverse drug reaction. A definitive diagnosis must await death and autopsy, when a pathologist can view the telltale "senile plaques" that pock the brains of Alzheimer's victim. Further, Varon et al. (Dev.

Neurosci., Vol. 6, pp. 73-100, 1983/1984) discuss the implications of neurotrophic and neurite-promoting factor and their clinical potential in neuronal diseases such as Parkinson, ALS and Alzheimer in which the authors concluded by stating that further clinical progress requires a better understanding of neurobiological bases of nerve regeneration. Furthermore, Cordell et al. (U.S. Patent No. 5,221,607) discuss that the etiology of Alzheimer's disease is unknown and up to date, there are no means available to treat the pathogenesis of Alzheimer's disease and the paucity of understanding concerning the mechanism of amyloid formation in Alzheimer's disease is a major obstacle in the development and design of therapeutic agents that can intervene in this process (See e.g., Col.1, lines 55-67).

Similarly, Nelson et al. (U.S. Patent No. 5,252,463) discuss serious diseases affecting the central nervous system, which referred as neuropathologies such as Alzheimer's disease and Down's syndrome in which the etiology of Alzheimer's disease is unknown (See e.g., column 1). Moreover, WO 99/21966 on page 3, lines15 to 24 states that to date, treatment for CNS disorders has been primarily via the administration of pharmaceutical compounds. Unfortunately, this type of treatment has been fraught with many complications including the limited ability to transport drugs across the blood-brain barrier and the drug-tolerance, which is acquired by patients to whom these drugs are administered long-term. For instance, Parkinson's patients using levodopa, become tolerant to the effects of levodopa, and therefore, steadily increasing dosages are needed to maintain its effect. In addition, there are a number of side effects associated with levodopa such as increased and uncontrollable movement.

Thus, the prior art clearly show the unpredictable nature and the complexity of the art in regard to treatment and/or promotion of neurite outgrowth of CNS disorders which include Alzheimer's disease, Parkinson's disease, Down's syndrome, Huntington's disease, etc. Therefore, considering the nature of the treatment and/or promotion of neurite outgrowth of CNS disorders and/or diseases by administering a therapeutically effective amount of the peptide claimed and the limited success achieved; one skilled in the art would not accept the instantly claimed invention as obviously valid and correct without demonstration of working example(s) or evidence or data for the following reasons:

In view of the fact that animals and humans are out bred, in view of the lack of disclosure of suitable animal models for a method of treating and promoting neurite outgrowth of CNS disorders or conditions or diseases, in view of the recognized problems in the art regarding effective treatment of diseases affecting the nervous systems (neuropathologies) and in view of the fact that it is difficult to regenerate the neurons in the living body; a reasonable doubt exists as to the enablement of the claimed method of treating a patient having a condition mediated by neurotoxicity, neurodegeneration or neurological damage by administering to said patient (particularly human) a therapeutically effective amount of a peptide comprising one or more monomeric peptides claimed. Thus, the claims are based on pure speculation that the method would be effective since Applicant has not established any *nexus* between an effective amount of the claimed peptides and its use in the manner claimed.

Further, the first paragraph of 35 U.S.C. 112 requires, *inter alia*, that a patent specification provide sufficient guidance to enable a person skilled in the art to make and use the claimed invention without undue experimentation. *In re Vaeck*, 947 F.2d 488, 495, 20 USPQ2d 1438, 1444 (Fed. Cir. 1991). While patent Applicants are not directed to disclose every species that falls within a generic claim, id. At 496, 20 USPQ2d at 1445, it is well settled that "the scope of the claims must bear a reasonable correlation to the scope of the enablement provided by the specification". *In re Fisher*, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970). Where practice of the full scope of the claims would require experimentation; factors to be considered in determining whether a disclosure would require undue experimentation ..... include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. *In re Wands*, 858 F. 2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

Therefore, in view of the above, and in view of the fact that there is no enablement in the instant specification for methods of treating and promoting neurite outgrowth diseases of the nervous system by administration of composition having the neurological therapeutic activity of EPO. Thus, applying the *Wands* factors to the facts of this case, one of skill in the art would find that undue amount of experimentation would be required to practice the full scope of the extremely broad claims fro the reasons given above. Hence, in view of the quantity of experimentation necessary, the

lack of adequate guidance or working example(s) or data or evidence, and the breadth of the claims, the claims are not commensurate in scope with the enabling disclosure. Accordingly, filing of evidence commensurate with the scope of the claims or amendment of the claims to what is supported by the enabling disclosure is suggested.

ARGUMENTS ARE NOT PERSUASIVE

CLAIMS REJECTION-35 U.S.C. 112 [1st] PARAGRAPH.

3. The rejection of newly submitted claims 38-52 under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for employing peptides comprising one or more monomeric peptides that bind to erythropoietin (EPO) receptor and use of said peptides in designing, synthesizing and testing of biological activity toward the EPO receptor *in vitro*, does not reasonably provide a method for treating a patient having a condition mediated by neurotoxicity, neurodegeneration or neurological damage by administering to said patient (which include humans) therapeutically effective amount of the specific compounds in the manner claimed in claims 38-51, and to a method of promoting neurite outgrowth in a patient having a condition mediated by neurotoxicity, neurodegeneration or neurological damage by administering to said patient effective amount of the specific compounds as claimed in claim 52. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Applicant's arguments filed 2/17/04 have been fully considered but they are not persuasive. Applicant has argued that 1) the Examiner has not provided a reasonable explanation as to why the scope of protection provided by a claim is not adequately enabled by the disclosure; 2) that there is no requirement in the patent laws that patentable inventions be problem-free, or that a patent specification address all potential problems that might be encountered in practicing an invention; 3) that the claims at issue are directed to methods for treating a patient having a condition mediated by neurotoxicity, neurodegeneration, or neurological damage and the term treating can refer to any *indicia* of success in the treatment or amelioration of a condition; 4) that enablement requires only that the application teach how to make and use the invention without undue experimentation; and 5) Applicant concludes by stating that the specification provides a full disclosure of the invention with respect of how to make and use the invention, and as such, the claims are, in fact, fully enabled by the specification as originally filed, and that the requirements of the first paragraph of 35 U.S.C. § 112 have been met is not persuasive.

Contrary to Applicant's arguments, the claims are directed to a method for treating a patient having a condition mediated by neurotoxicity, neurodegeneration or neurological damage by administering to said patient (which include humans) therapeutically effective amount of the specific compounds in the manner claimed in claims 38-51, and to a method of promoting neurite outgrowth in a patient having a condition mediated by neurotoxicity, neurodegeneration or neurological damage by administering to said patient effective amount of the specific compounds as claimed in

claim 52. The specification does not adequately teach a method for treating or promoting neurite outgrowth in a patient having a condition mediated by neurotoxicity, neurodegenaration or neurological damage, comprising administering to said patient a therapeutically effective amount of a peptide comprising one or more monomeric peptides as presently claimed in claims 38-52; rather, the specification teaches the expression of rhEPO in primary rat neuronal cultures and in neuronal cell lines (Example 1), EPO induced gene expression in PC12 cells (Example 2), rhEPO neuroprotection and neurite outgrowth effects on rat hipocampal and cortical cell and PC12 cells (Example 3), assays to show that EPO mimetic peptides stimulate neurite outgrowth in cell culture (Example 4), and assays to determine that EPO protects against ischemic injury in rats (Example 5).

Therefore, the instant specification does not commensurate with the claimed subject matter in which the peptides tested for biological activity against EPO receptors *in* vitro is expected to be particularly useful in the treatment of a patient having a condition mediated by neurotoxicity, neurodegeneration or neurological damage which encompass the various diseases and conditions recited on page 16, lines 27 to page 18, lines 30. Examples of the chronic neurodegenerative disorders, or diseases, or conditions intended to be treated by the peptides of the present invention include, but are not limited to, Alzheimer's disease, Pick's disease, diffuse Lewy body disease, progressive spranuclear palsy (Steel-Richardson syndrome), multisystem degeneration (SHY-Drager syndrome), chronic epileptic conditions associated with neurodegeneration, motor neuron diseases including amyotrophic lateral sclerosis,

degenerative ataxias, cortical basal degeneration, ALS-Parkinson's-Dementia complex of Guam, subacute sclerosing panencephalitis, Huntington's disease, Parkinson's disease, etc. Examples, of acute neurodegenerative disorders include, but are not limited to, various types of acute neurodegenerative disorders associated with neuronal cell death or compromise including cerebrovascular insufficiency, focal or diffuse brain trauma, diffuse brain damage, and spinal cord injury. With respect to the limitation of a condition mediated by neurotoxicity (claims 38 and 52), the claimed invention as recited on page 18, lines 10 to 15 in the instant specification contemplates the treatment and/or prevention of neurological and neuropsychiatric manifestations resulting from chemical, toxic, infections and radiation injury of the nervous system and as a result of prematurity, as well as the treatment and/or prevention of neurological and neuropsychiatric consequences of encephalopathies including, but not limited to, those of anoxic-ischemia, hepatic, glycemic, uremic, electrolyte and endocrine origin. Thus, there is no working example(s) or evidence or data to show that a similar regimen can be used for treating a patient (including a human) having a condition mediated by neurotoxicity, neurodegeneration or neurological damage such as Alzheimer's disease, Parkinson's disease, Huntington's disease, cerebrovascular insufficiency, anoxic-ischemia, etc., (as recited above) by administering to said patient a therapeutically effective amount of a peptide comprising one or more monomeric peptides, wherein each of the said monomeric peptides comprises the specific compounds in the manner claimed in claims 38-52.

With respect to Applicant's arguments that the Examiner has not provided a reasonable explanation as to why the scope of protection provided by a claim is not adequately enabled by the disclosure is unpersuasive. Contrary to Applicant's arguments, the Examiner has provided reasonable explanation as to why the scope of the claimed invention is broad and is not enabled for the method of treating diseases or conditions of the nervous system in patients by administration of compositions having neurological therapeutic activity of EPO compound claimed for the reasons discussed above. Therefore, in view of the above and in view of the contemporary knowledge in the art related to treating and/or promoting neurite outgrowth of neurodegenerative disorders such as Alzheimer's disease, Parkinson's disease, Huntington's disease, cerebrovascular insufficiency, anoxic-ischemia, etc. with the specific compounds claimed; the Examiner is unable to determine the enablement of the invention as claimed without appropriate working example(s) or evidence or data. Such evidence in the art of treating cognitive dysfunctions details the state of the art in this area and establishes that even some of the diseases such as Alzheimer's disease are very hard to diagnose, let alone to treat and/or promote neurite outgrowth in a patient having the above conditions (i.e., neurotoxicity, neurodegeneration, or neurological damage). For example, Ezzell (Scientific America, pages 152-153, March 7, 1993) states on page 152, middle column, before last paragraph that doctors can only diagnose Alzheimer's through a process of elimination, ruling out other disorders such as a slight stroke, a brain tumor, or even an adverse drug reaction. A definitive diagnosis must await death and autopsy, when a pathologist can view the telltale "senile plaques" that pock the

brains of Alzheimer's victim. Further, Varon et al. (Dev. Neurosci., Vol. 6, pp. 73-100, 1983/1984) discuss the implications of neurotrophic and neurite-promoting factor and their clinical potential in neuronal diseases such as Parkinson, ALS and Alzheimer in which the authors concluded by stating that further clinical progress requires a better understanding of neurobiological bases of nerve regeneration. Furthermore, Cordell et al. (U.S. Patent No. 5,221,607) discuss that the etiology of Alzheimer's disease is unknown and up to date, there are no means available to treat the pathogenesis of Alzheimer's disease and the paucity of understanding concerning the mechanism of amyloid formation in Alzheimer's disease is a major obstacle in the development and design of therapeutic agents that can intervene in this process (See e.g., Col.1, lines 55-67).

Similarly, Nelson et al. (U.S. Patent No. 5,252,463) discuss serious diseases affecting the central nervous system, which referred as neuropathologies such as Alzheimer's disease and Down's syndrome in which the etiology of Alzheimer's disease is unknown (See e.g., column 1). Moreover, WO 99/21966 on page 3, lines15 to 24 states that to date, treatment for CNS disorders has been primarily via the administration of pharmaceutical compounds. Unfortunately, this type of treatment has been fraught with many complications including the limited ability to transport drugs across the blood-brain barrier and the drug-tolerance, which is acquired by patients to whom these drugs are administered long-term. For instance, Parkinson's patients using levodopa, become tolerant to the effects of levodopa, and therefore, steadily increasing

dosages are needed to maintain its effect. In addition, there are a number of side effects associated with levodopa such as increased and uncontrollable movement.

Thus, the prior art clearly show the unpredictable nature and the complexity of the art in regard to treatment and/or promotion of neurite outgrowth of CNS disorders which include Alzheimer's disease, Parkinson's disease, Down's syndrome, Huntington's disease, etc. Therefore, considering the nature of the treatment and/or promotion of neurite outgrowth of CNS disorders and/or diseases by administering a therapeutically effective amount of the peptide claimed and the limited success achieved; one skilled in the art would not accept the instantly claimed invention as obviously valid and correct without demonstration of working example(s) or evidence or data for the following reasons:

In view of the fact that animals and humans are out bred, in view of the lack of disclosure of suitable animal models for a method of treating and promoting neurite outgrowth of CNS disorders or conditions or diseases, in view of the recognized problems in the art regarding effective treatment of diseases affecting the nervous systems (neuropathologies) and in view of the fact that it is difficult to regenerate the neurons in the living body; a reasonable doubt exists as to the enablement of the claimed method of treating a patient having a condition mediated by neurotoxicity, neurodegeneration or neurological damage by administering to said patient (particularly human) a therapeutically effective amount of a peptide comprising one or more monomeric peptides claimed. Thus, the claims are based on pure speculation that the

method would be effective since Applicant has not established any *nexus* between an effective amount of the claimed peptides and its use in the manner claimed.

Therefore, in view of the above, and in view of the fact that there is no enablement in the instant specification for methods of treating and promoting neurite outgrowth diseases of the nervous system by administration of composition having the neurological therapeutic activity of EPO; Applicant should present some data or authorative reference to establish the successful use of a method for treating and promoting neurite outgrowth in a patient having a condition mediated by neurotoxicity, neurodegeneration or neurological damage by administering the claimed peptide to a patient in order to fulfill 35 U.S.C. 112, first paragraph requirement. Secondly, the Examiner has clearly shown in the previous Office Action of Paper No. 23 (mailed 11/20/03) and as discussed above that without guidance through working example(s), one of ordinary skill in the art would not predict from background discussion and/or information and protocols to employ or administer the pharmaceutical formulation in therapeutically effective composition in the manner claimed. Thus, the specification does not enable any person skilled in the art to which it pertains, or which it is most nearly connected, to use the invention commensurate in scope with the claims. In the express absence of one or more examples, evidence and sufficient guidance, the skilled artisan would be faced with undue experimentation for practicing the invention. Thirdly, it is not understood from Applicant's response how the instant invention, which Applicant considers as novel and inventive, be exemplified without working example(s) or data or evidence. The law requires that a disclosure in an application shall inform

those skilled in the art how to use Applicant's alleged discovery, not how to find out how to use it for themselves. See *In re Gardner et al.*, 166 USPQ 138 (CCPA 1970). Therefore, undue experimentation is necessary to determine if and under what conditions, the claimed invention as broadly claimed is enabled. Hence, it is viewed that the specification does not enable the invention as claimed in claims 38-52, as it does not teach how to use the invention to achieve the function of the claims for the reasons discussed above. Thus, applying the Wands factors to the facts of this case, one of skill in the art would find that undue amount of experimentation would be required to practice the full scope of the extremely broad claims for the reasons given above. Hence, in view of the quantity of experimentation necessary, the lack of adequate guidance or working examples or data, and the breadth of the claims, the claims are not commensurate in scope with the enabling disclosure. Accordingly, filing of evidence commensurate with the scope of the claims or amendment of the claims to what is supported by the enabling disclosure is again suggested.

ACTION IS FINAL

4. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

CONCLUSION AND FUTURE CORRESPONDENCE

5. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Abdel A. Mohamed number is (703) 308-3966. The examiner can normally be reached on Monday through Friday from 7:30 a.m. to 5:00 p.m. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low, can be reached on (703) 308-2923. The appropriate fax phone number for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 305-7401 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196

Christopher S. Low

CHRISTOPHER S. F. LOW
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

AAM Mohamed/AAM

April 27, 2004